K010807

MAY - 3 2001

IRIS SURGICAL
446 Arricola ave. St. augustine, FL 32080
Tel: 904-827-1870 Fax: 904-827-1871

SUMMARY
PRE-MARKET NOTIFICATION- 510(K)
KILEJIAN CIRCUMCISOR

1- General Information

Trade Name:	KILEJIAN Circumcisor
Common Name:	Circumcision clamps
Classification Name:	Clamps, Circumcision

2- Establishment: **Iris Surgical**

Contact: V.John Kilejian M.D.
446 Arricola Ave.
St. Augustine, FL 32080
Tel: 904-827-1870, Fax: 904-827-1871

Registration #: Enclosure # 1

3-Classification: A similar device, the **Gomco Circumcision Clamp,** (Encl.# 4) has been classified as Class II device under 21 CFR 884.4530

Classification No: Clamp, Circumcision -85HFX

Performance Standard: None. No government, industry or voluntary standards have been established for this product.

Description of The Kilejian Circumcisor. Circumcision is a procedure generally performed in the newborns and less frequently in older males. It is defined as circumferential excision of the foreskin or prepuce at or near the level of coronal sulcus, with minimal amount of preputial skin remaining. This should be accomplished under sterile conditions, with precision and without blood loss.
The Circumcisor is a simple disposable mechanical device, made of polycarbonate alloy . It allows the circumferential crushing of the prepuce (foreskin) of a newborn near the level of corona with precision. The circumcisor is composed of two pieces. (See description pp. 4-8).

K016867

1. The Bell, which is inserted around the glans of the penis, inside the prepuce.
2. the Body of the device, which is doughnut shaped and surrounds the prepuce. Within the body of the device, 6 pie shaped crushing blades converge centrally and form a perfect circle around the bell. The two parts of the device, the bell and the body , are anchored to each other, thus defining the level of the circumcision. The prepuce is crushed between the outer wall of the Bell and the converging dull blades with a thickness of 0.030 inches or 0.75 mm. The prepuce is excised with a scalpel distal to the level of the crushing blades. (see Procedure Encl # 5)

Substantial Equivalence: The Kilejian Circumcisor is substantially equivalent to the **Gomco Circumcision Clamp** (Encl.# 4) being supplied by VES International Texas, Inc. The earliest 510(k) Document Control Number we could find, is under the name of Zinnanti Surgical Instruments, 510(k) # K-894201.

The Gomco Circumcision Device is a legally marketed device for the past one half a century. (Encl. # 4) It is made of multiple reusable metal parts including a bell and the baseplate.The mechanism of action is to crush the preputial skin around the rim of the bell and an appropriate sized hole in the base plate. The width of the crushed prepuce at the rim is 0.030 inches or 0.75 mm.

The Kilejian circumcisor and the Gomco device are substantially equivelent in performance of circumcision. They are used for circumferencial crushing of the prepuce. They differ in their mechanism of action. The Gomco device crushes the prepuce parallel to the axis of the penis while the Kilejian Circumcisor crushes the prepuce perpenducular to the axis of the penis. The advantage of the latter is the ability for visual inspection of every step in performance of the circumcision and human factors considerations. Other adventages of the Kilejian Circumcisor include two piece construction vs. multiple pieces for Gomco . In addition, sterile, disposable use of the Kilejian Circumcisor is safer compared to the re-usable metal construction of the Gomco, with associated inherent risk of mismatching sizes of different components during reprocessing and wearing of the contact points (see encl # 6, director's warning).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2001

V. John Kilejian, M.D.
President
Iris Surgical
446 Arricola Avenue
ST AUGUSTINE FL 32080-4566

Re: K010867
Kilejian Circumcisor
Dated: March 19, 2001
Received: March 22, 2001
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HFX

Dear Dr. Kilejian:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010867

Device Name: KILEJIAN CIRCUMCISOR

Indications For Use:

The only indication for use of KILEJIAN CIRCUMCISOR is CIRCUMCISION: Circumcision is a procedure generally performed in the newborns and less frequently in older males. It is defined as circumferential excision of the foreskin or prepuce at or near the level of coronal sulcus, with minimal amount of preputial skin remaining. This should be accomplished under sterile conditions, with precision and without blood loss.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010867

Prescription Use ✓
(Per 21 CFR 801.109)